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10/590,866	09/19/2006	Henry William Lupton	LRM-36143-A-US	8975

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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02/08/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/590,866	Applicant(s) LUPTON ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/20/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Re-opening Prosecution

1. This Office Action is responsive to the interview summary mailed 10/19/2010 and the interview summary filed 11/19/2010, wherein it was agreed to re-open prosecution and issue a new Office Action.
2. The Final Office Action mailed 08/05/2010 is hereby **vacated** and prosecution on the merits is hereby *re-opened*.
3. This Office Action is responsive to the amendments filed 05/27/2010. The following new and/or reiterated ground(s) of rejection is/are set forth:

Priority

4. The instant application 10/590,866 filed 09/19/2006 is a national stage entry of PCT/IE05/00031 filed 03/24/2005 which claims foreign priority to S2004/0201 filed in Ireland on 03/26/2004.
5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

6. The information disclosure statement(s) (IDS) submitted on 09/20/2010 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “magnetic urging means for urging the terminal member” and “the guidewire of magnetic material” of claims 105-106 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 90, 93, 94-97, 99, 100, 103, 105, and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

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USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

12. In the present instance, claim 90 recites the broad recitation in the range of 1 to 90 degrees, and the claim also recites in the range of 30 to 90 degrees which is the narrower statement of the range/limitation. The scope of the claim is indeterminate.

13. The term(s) "preferably" and/or "advantageously" in claim(s) 93 and 94 are relative terms which render the claim(s) indefinite. The term(s) "preferably" and/or "advantageously" are not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The scope of the claimed invention is indeterminate with respect to whether or not the limitations following the relative terms may or may not be required to be included or excluded in the scope of the invention.

14. The scope of claim 99 is indeterminate because the claim language is indefinite with respect to the structured required by "the leading edge portion" being both "convex in plan view" and "concave in plan view".

15. The term(s) "substantially similar" in claim(s) 100 and 103 is/are relative terms which render the claim(s) indefinite. The term(s) "substantially similar" are not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The scope of the claimed invention is indeterminate with respect to degree of similarity or lack thereof required for the claim language.

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16. With respect to claims 105 and 106, claim element “magnetic urging means for urging located externally of the subject for urging the terminal member” is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. Conversely, the written description merely states that “a magnetic urging means” is located externally of the subject and is for urging a magnetic guidewire and especially the terminal portion thereof through a vascular occlusion. The written description does not appear to even attempt to describe any structure(s) for the function.

Applicant is required to: (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or (b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either: (a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or (b) Stating on the record what the

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corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 87-102 and 104-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Tillander (US 3,674,014) as broadly as structurally claimed.

19. Initially the Examiner notes the presence of the transitional term “characterised in that”. The term is being treated on the merits as being inclusive and open-ended and not excluding the presence of additional unrecited elements, similar to “comprising” (see MPEP 2111).

20. For claim 87, Tillander discloses a guidewire (1) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) for use in a re-canalizing process for re-canalizing a vascular occlusion in a human or animal subject, the guidewire extending between a proximal end (as best seen in Figures 1-2) and a distal end (as best seen in Figures 1-2), and defining a longitudinally extending main central axis (as best seen in Figures 1-2), characterized in that *inter alia* the guidewire terminates at the distal end in a terminal

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member (3) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) extending axially from the guidewire (as best seen in Figures 1-2), the terminal member tapering to a distal leading edge portion (4a) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) for engaging and gradually opening the occlusion as the terminal member is urged therethrough (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

21. For claim 88, Tillander discloses a guidewire, in which the leading edge portion is an elongated leading edge portion (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

22. For claim 89, Tillander discloses a guidewire, in which the leading edge portion extends in a direction at an angle relative to an axial direction defined by the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

23. For claim 90, Tillander discloses a guidewire, in which the leading edge portion extends in a direction at an angle in the range of 1° to 90° relative to an axial direction defined by the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

24. For claim 91, Tillander discloses a guidewire, in which a first surface portion (a first surface side portion of 4a) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) of the terminal member converges towards an opposite second surface portion (a second, opposite surface side portion of 4a) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) thereof towards the leading edge portion.

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25. For claim 92, Tillander discloses a guidewire, in which the distal portion of the first surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

26. For claim 93, Tillander discloses a guidewire, in which a distal portion of the second surface portion of the terminal member is concave (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

27. For claim 94, Tillander discloses a guidewire, in which the first and second surface portions of the terminal member are joined by spaced apart opposite third (a third surface side portion of 4a) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) and fourth (a fourth, opposite the third surface side portion of 4a) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) surface portions, the leading edge portion of the terminal member extends between the third and fourth surface portions (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

28. For claim 95, Tillander discloses a guidewire, in which the third and fourth surface portions of the terminal member are parallel to each other in an axial direction defined by the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

29. For claim 96, Tillander discloses a guidewire, in which the third surface portion of the terminal member is convex in a longitudinal direction relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

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30. For claim 97, Tillander discloses a guidewire, in which a distal portion of the third surface portion of the terminal member is concave in a longitudinal direction relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), a proximal portion of the third surface portion of the terminal member being in a longitudinal direction relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the fourth surface portion of the terminal member being convex in a longitudinal direction relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

31. For claim 98, Tillander discloses a guidewire, in which the leading edge portion is radiused from the first surface portion of the terminal member to the second surface portion thereof (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

32. For claim 99, Tillander discloses a guidewire, in which the leading edge portion is radiused in plan view (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the leading edge portion is convex in plan view (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), and the leading edge portion is concave in plan view (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

33. For claim 100, Tillander discloses a guidewire, in which the maximum outer transverse cross-sectional area of the terminal member is substantially similar to the outer transverse cross-sectional area of the guidewire adjacent the terminal member (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

34. For claim 101, Tillander discloses a guidewire, in which the guidewire comprises an elongated core wire (2) (as best seen in Figures 1-2) (column 2 line 51 – column 3

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line 31) extending from the proximal end to the distal end, the terminal member is secured to the distal end of the core wire (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the core wire terminates in a distal portion of rectangular transverse cross-section defining first and second opposite major surfaces (about 10) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) joined by first and second opposite minor surfaces (about 10) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) for facilitating bending thereof (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), for offsetting the terminal member relative to the main central axis (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), for facilitating guiding of the terminal member into a branched vessel of a vascular system (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), and a reinforcing means (10) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) being provided on the distal portion of the core wire for minimizing axial twisting thereof (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

35. For claim 102, Tillander discloses a guidewire, wherein the first and second major surfaces of the distal portion of the core wire define therebetween a central major plane extending parallel to the main central axis and cutting the first and second minor surfaces (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), and the distal portion being curved in the central major plane for offsetting the terminal member relative to the main central axis for facilitating guiding of the terminal member into a branched vessel of a vascular system (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

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36. For claim 104, Tillander discloses a guidewire, in which a core wire (2) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) engaging bore extends into the terminal member for engaging the distal end of the core wire (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the terminal member being secured to the core wire by frictional adhesive (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

37. For claim 105, Tillander discloses a guidewire, in which at least a portion of the terminal member is of radiopaque material (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), and a distal portion of the guidewire is of a magnetic material for facilitating urging of the terminal member through a vascular system by a magnetic urging means located externally of the subject (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

38. For claim 106, Tillander discloses in combination the guidewire as claimed in claim 105 and a magnetic urging means for urging the terminal member through a vascular occlusion (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the magnetic urging means urging the terminal member through a vascular system to the vascular occlusion (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

39. For claim 107, Tillander discloses a method for re-canalizing a vascular occlusion in a human or animal subject, the method comprising *inter alia* urging the terminal member of the guidewire of claim 87 through the occlusion for gradually opening thereof (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the terminal

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member being urged by the guidewire through the vascular system to the occlusion prior to being urged through the occlusion (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

Claim Rejections - 35 USC § 103

40. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

41. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

42. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tillander (US 3,674,014) in view of Wagner et al. (US 5,135,483, hereinafter Warner).

43. For claim 103, Tillander discloses a guidewire, further comprising a sleeve (4b) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) extending along the core wire from the terminal member and terminating at a location intermediate the distal

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end and the proximal end of the core wire (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the sleeve being of external circular transverse cross-section (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), the external diameter of the sleeve being substantially similar to the diameter of the terminal member adjacent the guidewire (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31), a plug (5 adjacent 4b) (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31) extending from the terminal member adjacent a proximal end thereof for engaging an internal bore defined by the sleeve for securing the sleeve to the terminal member (as best seen in Figures 1-2) (column 2 line 51 – column 3 line 31).

44. For claim 103, Tillander discloses the claimed invention as set forth and cited above except for expressly disclosing the sleeve comprising a helical coil located around the core wire adjacent the distal end thereof. Although Tillander is silent with respect to the sleeve comprising a helical coil, Tillander is expressly concerted with configuring to assist in the bending of the terminal member relative to the axial direction of the elongated core wire.

45. For claim 103, Wagner teaches a guidewire, comprising *inter alia*: a sleeve (64) (as best seen in Figures 5 and 7) (column 4 line 49 – column 5 line 23) comprising a helical coil (64) (as best seen in Figures 5 and 7) (column 4 line 49 – column 5 line 23) located around a core wire (26) (as best seen in Figures 5 and 7) (column 4 line 49 – column 5 line 23) adjacent the distal end thereof.

46. For claim 103, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with

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no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Tillander and Wagner. The only difference is the combination of the component parts into a single device. It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Tillander with the components as taught by Wagner to achieve the predictable results of providing an alternate dimensioned sleeve in order to aid the guidewires traversal of tortuous vasculature.

Response to Arguments

47. Applicant's arguments with respect to claims 87-107 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

48. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G. Hoekstra/
Primary Examiner, Art Unit 3736